

Recombinant DNA Advisory Committee Submission

BB IND 8028

Protocol Number TG1041.01

Protocol Title: Phase I/Trial of Immunotherapy with Adenovirus-Interferon- γ (TG1041) in Patients with Malignant Melanoma

Non-Technical Abstract

This study involves the use of an experimental product, Adenovirus-Interferon- γ (code number TG1041), to determine if it is safe and if this therapy, injected into a melanoma tumor, can help stimulate the body's immune system to help it fight the cancer. Patients with malignant melanoma who have metastatic or locally recurrent disease that is not expected to be cured with standard forms of therapy may be eligible to enroll into this study. The treatment involves an adenovirus vector (delivery system) containing the human gene for interferon- γ . Interferon- γ is a naturally occurring substance that stimulates the immune system. The adenovirus used for this product comes from a group of viruses usually responsible for minor diseases such as the common cold. The adenovirus has been altered to prevent it from causing these types of infections.

TG1041 is given as a shot directly into a tumor once a week for 3 weeks. The first three patients will receive the lowest dose, 1×10^7 i.u. If, after all 3 patients have received and tolerated all 3 injections, the next three patients will be entered into the study and will receive the next dose level. This procedure will continue until the 1×10^{10} dose level is reached, unless severe toxicity to one of the doses is observed. If severe toxicity is seen, no further dose escalation will occur.